ATTORNEY DOCKET NO. PNC-002

PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Benjamin WOLOZIN et al.

Serial Number: 09/901,187 Group Art Unit: 1646

Filed: July 9, 2001 Examiner: O. Chernyshev

For: METHODS FOR PREVENTING NEURAL TISSUE DAMAGE AND FOR THE TREATMENT OF ALPHA-SYNUCLEIN DISEASES

PETITION UNDER 37 C.F.R. § 1.181(a)(3) AND UNDER 37 C.F.R. § 1.183 TO WITHDRAW OFFICE ACTION AND ISSUE NEW ACTION

Assistant Commissioner
for Patents
Washington, D.C. 20231

November 4, 2002

Sir:

Applicants petition under 37 C.F.R. § 1.181(a)(3) and, as necessary, under 37 C.F.R. § 1.183 that the Office Action dated July 3, 2002, be withdrawn and that a new action be issued which sets forth proper restriction and election of species requirements.

I. STATEMENT OF FACTS

(A) An Office Action was issued in this application on July 3, 2002.

(B) The Action requires restriction to one of forty-five allegedly independent and distinct inventions identified as follows:

(I) Claims 1-11, identified as being directed to a method for determining whether an agent is capable of inhibiting the aggregation of α-synuclein;

(II) Claim 12-15, identified as being directed to a kit for testing aggregation of α-synuclein;

(III-XV) Claims 16-29, identified as being directed to a method for treating a neurodegenerative disease by administration of any one of the twelve peptide sequences recited therein;

(XVI) Claims 30 and 32, identified as being directed to a method for inhibiting the formation of aggregates of α-synuclein;

(XVII) Claim 31, identified as being directed to a method for inhibiting the formation of

aggregates of α-synuclein;

(XVIII-XXX) Claims 33-38, identified as being directed to a composition of Mg2+ and any one of the twelve peptide sequences recited therein;

(XXXI-XLIII) Claims 39-45, identified as being directed to any one of the twelve peptide sequences recited therein;

(XLIV) Claims 47-50, identified as being directed to a method for identifying peptides that are useful in inhibiting the formation of aggregates of α-synuclein which involves a peptide; and

(XLV) Claim 51, directed to a method for determining the inhibition of aggregation of α-synuclein.

(C) Claims 16, 17, 18, 19, 20, 24, 28 and 29 are not directed to a method for treating a nondegenerative disease limited to administration of peptides and, particularly, to one of twelve peptides.

(D) Claims 33, 34 and 38 are not directed to a composition of Mg2+ and one of twelve peptides.

(E) Claims 39 and 43 are not limited to twelve peptides.

(F) The Action states, without explanation, that "inventions" I, III-XVII, XLIV and XLV are unrelated, that "inventions" II and XVIII-XLIII are unrelated; that "inventions" I and II are related as product and process of use; and that "inventions" III-XVII and XVIII-XLIII are related as product and process of use, but does not explain why, for example, Group (III) is independent and distinct from each of Groups (IV) to (XV); why Group (XVIII) is independent and distinct from each of Groups (XIX)) to (XXX) or why Group (XXXI) is independent and distinct from each of Groups (XXXII)) to (XLIII).

(G) The Action also requires an election of species if Group (I) or Group (III) is elected, but identifies the alleged patentably distinct species as "different methods of determination of α-synuclein aggregation" and "different neurodegenerative disorders", respectively, without an explanation of why these different methods and disorders are patentably distinct.

(H) The action alleges that claims 21, 22, 25, 26, 35, 36,

40, 41, 44 and 45 are improper Markush claims because the plurality of amino sequences recited in these claims lack a common utility.

(I) Each of the plurality of amino sequences recited in the allegedly improper Markush claims is identified as an agent that inhibits the formation of α-synuclein aggregates (see claims 16 and 33).

(J) Responsibility for this application was transferred to the undersigned more than two months after the date of the action.

II. POINT TO BE REVIEWED

Applicants request that the restriction and election of species requirements be reviewed for compliance with the rules and guidelines for restriction and election of species requirements.

III. ACTION REQUESTED

Applicants request that the action of July 3, 2002, be withdrawn and that a new action be issued which explains why each invention, i.e., each of Groups (I)-(XLV), is patentably distinct from each of the other inventions, i.e., the other of Groups (I)-(XLV), such that applicants (A) can make a determination of (1) whether the different "inventions" have been properly shown to be independent and/or distinct and (2) whether the different species

have been properly shown to be patentably distinct and(B) can make a reasoned election or elections with or without traverse.

IV. BRIEF ARGUMENTS IN SUPPORT OF PETITION

The Office has not properly explained why each invention identified in the action is independent and distinct from each other invention identified in the action, or why the species identified in the action are patentably distinct, and has not provided a proper basis for limiting any of the claims to one of twelve peptides identified in certain of the claims. The claims reciting the peptides are proper Markush claims because each of the peptides has a common utility as an agent for inhibiting the formation of α-synuclein aggregates. The claims that do not recite the peptides are not Markush claims.

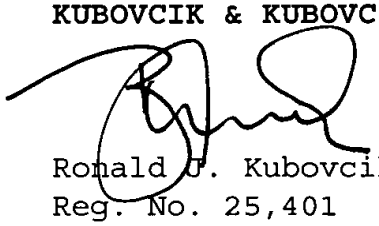
As an example, claim 16 recites a method for treating a neurodegenerative disease that involves the formation of Lewy bodies, the method comprising administering to a patient in need thereof one or more agents that inhibit the formation of α-synuclein aggregates. Claim 17 defines the agent as Mg2+ and claim 19 identifies the agent generally as a peptide. No reasoning has been given as to why each of claims 17 and 19 is independent and/or

distinct from claim 16 or why limiting any of these claims to one of the twelve peptides recited in claim 21 is properly required under the rules. Similar considerations apply to other of the inventions identified by the Office.

In the event any fees are required in connection with this petition, the Office is authorized to charge the fee to Deposit Account No. 111833.

Respectfully submitted,

KUBOVCIK & KUBOVCIK



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